REMARKS

Claims 1 and 5-11 constitute the pending claims in the present application. Among them, Claims 7 and 10 are directed to non-elected species, and are withdrawn from further consideration.

Applicant respectfully requests reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Claim Rejections under 35 U.S.C. § 102

Claims 1, 5, 6, 8, 9, and 11 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by International Patent Application Publication WO 03/097011 A1 ("Barth"). The Office Action alleges that Barth "discloses a method of treating gastroesophageal reflex disease (GERD) ... sleep disorders, sleep apnea and snoring..." The Office Action cited certain passages of Barth to support this contention.

Applicant has previously argued, and hereby reiterate that the pending claims as amended are directed to the treatment of snoring patients *regardless of whether they may or may not have sleep apnea* (and regardless of whether they may or may not have GERD). Barth cannot anticipate the claimed invention, because Barth fails to disclose the treatment of snoring regardless of the existence of sleep apnea with the subject agents.

The Office Action asserts that "there is no *de minimus* requirement as to how many times a reference must explicitly state a claim limitation before said reference becomes an anticipatory piece of prior art."

However, the Office Action has misunderstood Applicant's argument. Here, Applicant is not arguing that a single reference to "snoring" is insufficient for Barth to become an anticipatory refererence. Instead, Applicant is arguing that Barth simply fails to disclose even *once* the use of the subject agents to directly reduce snoring, *regarless of whether the snoring is associated with or caused by sleep apnea.*

As argued before, the single reference to "snoring" in Barth appears in page 8, the second full paragraph (line 14): "[i]n other embodiments, the invention provides methods for treating and

preventing one or more symptoms associated with or caused by sleep apnea ... Physical signs that suggest obstructive sleep apnea syndrome or obstructive sleep apnea include loud snoring, witnessed apneic episodes, obesity, excessive daytime sleepiness, and nocturnal snorting and gasping" (emphasis added). The whole paragraph is clearly discussing the symptoms associated with or caused by sleep apnea, as opposed to these symptoms independent of sleep apnea, or these symptoms as caused by some other diseases.

Obviously, *in this context*, this disclosure never amounts to the teaching that certain "physical signs" that merely suggest the presence of sleep apnea, such as *obesity* or *loud snoring*, can be treated *directly* with those agents. In other words, in view of Barth, a skilled artisan (such as a physician) would at most prescribe the subject agents to a *sleep apnea patient*, regardless of whether this patient also snores. However, this same physician would not subscribe the subject agents to a *snoring patient* seeking help to reduce snoring, because nowhere in Barth is the teaching that the subject agents can also be used directly to treat snoring, just like nowhere in Barth is the teaching that the subject agents is an obesity drug that can be used directly to treat obesity. If one were to conclude that Barth teaches the direct treatment of snoring with such agents (which is does not), then one would have to conclude that Barth also teaches the treatment of obesity with such agents (which it does not).

To illustrate further, suppose there are three patients, I, II, and III, each having the following conditions, respectively: sleep apnea only, sleep apnea and snoring, and snoring only.

	Apnea ONLY (I)	Apnea / **Snoring** (II)	**Snoring ONLY** (III)
Barth	YES	YES	NO
Claim	NO	**YES**	**YES**

Barth describes the use of treating patient I (no snoring problem) and patient II (with snoring problem), both are sleep apnea patients. However, Barth does not teach the treatment of patient III, which has no sleep apnea. In contrast, the presently claimed invention with respect to the treatment of snoring applies to all snoring patients, regardless of whether they happen to exhibit sleep apnea, *i.e.*, patients II and III.

As argued before, the prevalence of snoring is much greater than that of obstructive sleep apnea or OSAS. In fact, the majority of patients with a snoring disorder do not have clinically detectable or significant sleep apnea. In a 1995 study by Bearpark *et al.* (*Am. J. Respir. Crit. Care Med.* **151(5)**: 1459-65, 1995, abstract submitted herewith as **Exhibit A**), the authors concluded that "a high percentage of snoring is not essential for the occurrence of sleep apnea, nor does it necessarily indicate that apnea is present." Thus snoring is neither necessary nor sufficient for sleep apnea, and snoring and sleep apnea are independent conditions that may or may not co-exist in a patient.

Because of this, Barth cannot inherently anticipate the claimed invention, simply because *some* but not all sleep apnea patients are *sometimes* treated for their snoring problem. Barth at best teaches the treatment of sleep apnea patients, who may or may not have snoring problem. Pursuant to MPEP 2112, "[t]he fact that a certain results or characteristics may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)" (emphasis in original).

In fact, based on the same reasoning, Applicant has previously argued that Rubin does not inherently anticipate the claimed invention. The Examiner agrees that, by amending the claims to include "in need thereof," the rejection based on Rubin would be overcome.

To expedite prosecution, Applicant has adopted the Examiner's suggestion to amend Claim 1 and to overcome the anticipatory rejection based on Rubin. Applicant submits that the amendment would also overcome the anticipatory rejection based on Barth for the same reason.

Therefore, neither Barth nor Rubin anticipate the claims as amended. Reconsideration and withdrawal of this objection are respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1, 5, 6, 8, 9, and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Patent Application Publication WO 03/053221 A2 ("Ieni") in view of either Senior *et al.* or Xiao *et al.* The Office Action argues that "snoring is a symptomatic condition intrinsically associated with OSAS, administration of a therapeutically effective amount of a proton pump

inhibitor, such as lansoprazole and omeprazole, would intrinsically treat not only OSAS, but also symptomatic conditions intrinsically associated therewith, such as snoring, as instantly claimed."

Applicant submits that this rejection is essentially the same as that based on Barth or Rubin, and thus would also be overcome by the Claim 1 amendment above. Briefly, even assuming for the sake of argument that there is motivation to combine Ieni and Xiao / Senior, the combination still fails to teach all the limitations of the claimed invention. As argued above, although *some* but not all of the OSAS (obstructive sleep apnea syndrome) patients may snore, a method of treating OSAS patients cannot inherently anticipate a method of treating snoring patients for the same reason argued above. *See* MPEP 2112, "[t]he fact that a certain results or characteristics may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)" (emphasis in original).

Thus at least one of the three requirements for establishing a *prima facie* case of obviousness has not been met. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the above amendments, Applicant believes the pending application is in condition for allowance. Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. **18-1945**, from which the undersigned is authorized to draw under Order No. **SOHN-P01-001**.

Dated: January 17, 2007

Respectfully submitted,

By_____

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1: Am J Respir Crit Care Med. 1995 May;151(5):1459-65. Linl

Snoring and sleep apnea. A population study in Australian men.

Bearpark H, **Elliott L**, **Grunstein R**, **Cullen S**, **Schneider H**, **Althaus W**, **Sullivan C**.

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Snoring and sleeping apnea are reportedly associated with morbidity. We used home monitoring (MESAM IV) to measure snoring and sleep apnea in 294 men aged 40 to 65 yr from the volunteer register of the Busselton (Australia) Health Survey. In this group, 81% snored for more than 10% of the night and 22% for more than half the night; 26% had a respiratory disturbance index (RDI) > or = 5, and 10% had an RDI > or = 10. There was a relatively low correlation between percentage of night spent snoring and RDI (rho = 0.47, $p < 0.005$). Subjective daytime sleepiness plus RDI > or = 5 occurred in a minimum of 3%. Obesity was related to snoring, RDI, and minimum SaO2 (all $p < 0.0001$). There was no relationship between age and either RDI or snoring, but increased age was related to minimum SaO2 < 85% ($p < 0.05$). Alcohol consumption was not related to sleep-disordered breathing. Smokers snored for a greater percentage of the night than nonsmokers (41 versus 31%, $p = 0.01$). We conclude that, in middle-aged men, both snoring and sleep apnea are extremely common, and in this age range both are associated with obesity but not with age. However, a high percentage of snoring is not essential for the occurrence of sleep apnea, nor does it necessarily indicate that apnea is present.

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